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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S.

Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESS: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Personalized Body Weight Management System Using Monitoring Devices and Mathematical Models of Metabolism

Description of Technology: Attempts to manage body weight are often unsuccessful or only temporary. This is, in part, due to antiquated dieting methods that attempt to address calorie consumption while ignoring metabolic and physical changes. It is becoming clear that personalized methods to manage body weight must be developed.

Scientists at the NIH have developed new methods for prescribing and monitoring personalized weight management interventions. The system uses validated mathematical models of human metabolism to set weight management goals and predict individual body weight outcomes in the context of changing metabolic needs and calorie consumption. The system uses repeated monitoring of a patient's body weight to assess progress and provide specific feedback to the patient and health care professional. Projected outcomes and body weight goals can be revised over time along with required prescription modifications to meet the body weight goals. The system is integrated into a network of one or more devices that may additionally monitor various physiological parameters, physical activities, food intake, or other behaviors. Such an enhanced personalized weight management program has great promise in the management of obesity.

Potential Commercial Applications:

- Devices - Weight management diagnostic
- Software for the integration of multiple devices

Competitive Advantages: Integrated system provides feedback to health care professional and patient with more accurate predictors of weight loss outcomes. Combined with other devices, patient receives encouragement to stay on track.

Inventor: Kevin D. Hall (NIDDK)

Publications:

1. Hall KD, Sacks G, Chandramohan D, Chow CC, Wang YC, Gortmaker SL, Swinburn BA. Quantification of the effect of energy imbalance on bodyweight. *Lancet*. 2011 378 (9793):826-837. [PMID 21872751]

2. Hall KD and Chow CC. Estimating changes in free-living energy intake and its confidence interval. *Am J Clin Nutr*. 2011 Jul;94(1):66-74. [PMID 21562087]

3. Hall KD. Predicting metabolic adaptation, body weight change, and energy intake in humans. *Am J Physiol Endocrinol Metab*. 2010 Mar;298(3):E449-466. [PMID 19934407]

Intellectual Property: HHS Reference No. E-063-2012/0 — U.S. Provisional Application No. 61/592,325 filed 30 Jan 2012

Licensing Contact: Michael A. Shmilovich, Esq., CLP; 301-435-5019; shmilovm@mail.nih.gov

Collaborative Research Opportunity: The NIDDK Laboratory of Biological Modeling is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Marguerite J. Miller at 301-496-9003 or millermarg@niddk.nih.gov.

Direct Impact Spark Ionization (DISI) Mass Spectrometry (MS) for Identification of Microbes

Description of Technology: Generating reproducible mass spectra from bacterial samples in a timely fashion at atmospheric pressure remained problematic for many years. FDA/NCTR inventors designed a rapid mass spectrometry device using direct impact spark ionization source for microbial analytes identification via spectral pattern recognition. The device design includes a rapid mass spectrometer suitable for analyzing microbiological samples that was earlier used to analyze low volatile organic compounds. The device employs a solid needle for electrode discharge. It includes a gear plate that introduces stainless steel pins carrying bacterial samples. The pins also act as counter electrodes and are targeted by controlled arcs. The small custom-made glass cylinder that is meant to shut out oxygen and prevent the introduction of ambient moisture into the analyte is unique from other DISI device. The examination revealed enormous peak intensity and spectral information with normal ionization mode on the same instrument. This device can be employed in fields such as pathogen determination in clinical settings, QA/QC (of drugs, food or cosmetic ingredients), continuous monitoring of (airborne) Biological Warfare Agents and the like.

Potential Commercial Applications:

- Pathogen detection,
- QA/QC (of drugs, food or cosmetic ingredients),
- Continuous monitoring of (airborne) Biological Warfare Agents and the like.

Competitive Advantages:

- Rapid, specific, sensitive and reproducible identification of microbiological analytes

- Systematic acquisition of reproducible spectra among same bacterial species
- Whole cell analysis of food-borne pathogens is rapid, safer and micro-reliable
- Characteristic mass spectra obtained and reproduced for food-borne pathogens
- Unique DISI device with gas cylinder chamber

Development Stage:

- Prototype
- In vitro data available

Inventors: Peter Alusta, Cameron Dorey, Ryan Parker, Dan A. Buzatu, Jon G. Wilkes (all of FDA/NCTR)

Intellectual Property: HHS Reference No. E-258-2011/0 — U.S. Patent Application No. 13/271,182 filed 11 Oct 2011

Related Technologies:

- HHS Reference No. E-169-2000/0 — U.S. Patent Application No. 09/975,530 filed 10 Oct 2001

- HHS Reference No. E-259-2011/0 — U.S. Provision Application No. 61/564,926 filed 30 Nov 2011

Licensing Contact: Michael A. Shmilovich, Esq., CLP; 301-435-5019; shmilovm@mail.nih.gov

Collaborative Research Opportunity: The NCTR/FDA inventors are seeking statements of capability or interest from parties interested in collaborative research to

further develop, evaluate or commercialize this device. For collaboration opportunities, please contact Alice Y. Welch, Ph.D. at Alice.Welch@fda.hhs.gov.

Method of Treating Hepatitis C Virus Infection With a Small Molecule CHK2

Inhibitor

Description of Technology: DNA damage sensors such as Checkpoint Kinase 2 (Chk2) are key regulators of the cellular DNA damage response that limits cell-cycle progression in response to DNA damage. It has been reported that these DNA damage sensors also play a key role in Hepatitis C virus (HCV) replication. The subject technology are small molecule CHK2 kinase inhibitors that have been shown to have promising activity against HCV replication. The compounds were discovered by high throughput screening of chemical libraries with more than 150,000 compounds. These novel compounds can potentially be used in combination with other anti-HCV drugs or interferon and represent a novel target for treating HCV. *In vitro* antiviral assay data, as well as preliminary *in vitro* and *in vivo* pharmacokinetic data are available upon request.

Potential Commercial Applications: The subject technology can potentially be developed into anti-HCV therapeutics, particularly in combination with other anti-HCV therapeutics.

Competitive Advantages: The subject technology represents a novel and promising target for treating HCV infection and thus, has the potential to increase the efficacy of other HCV antivirals that directly target HCV in a multi-drug formulation. Furthermore, since the subject technology targets a cellular protein necessary for HCV

replication and not the virus itself, the emergence of viral resistance against the subject technology could be low or more delayed.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Yves G. Pommier, Robert H. Shoemaker, Dominic A. Scudiero, Andrew G. Jobson, David S. Waugh, George T. Lountos (all of NCI)

Publications:

1. Jobson AG, et al. Identification of a Bis-guanylhyazone [4,4'-Diacetyldiphenylurea-bis(guanylhyazone); NSC 109555] as a novel chemotype for inhibition of Chk2 kinase. Mol Pharmacol 2007 Oct;72(4):876-884. [PMID 17616632]
2. Jobson AG, et al. Cellular inhibition of checkpoint kinase 2 (Chk2) and potentiation of camptothecins and radiation by the novel Chk2 inhibitor PV1019 [7-nitro-1H-indole-2-carboxylic acid {4-[1-(guanidinohyazone)-ethyl]-phenyl}-amide]. J Pharmacol Exp Ther. 2009 Dec;331(3):816-826. [PMID 19741151]
3. Lountos GT, et al. Crystal structure of checkpoint kinase 2 in complex with NSC 109555, a potent and selective inhibitor. Protein Sci. 2009 Jan;18(1):92-100. [PMID 19177354]
4. Lountos GT, et al. X-ray structures of checkpoint kinase 2 in complex with inhibitors that target its gatekeeper-dependent hydrophobic pocket. FEBS Lett. 2011Oct 20;585(20):3245-3249. [PMID 21907711]

5. Lountos GT, et al. Structural characterization of inhibitor complexes with checkpoint kinase 2 (Chk2), a drug target for cancer therapy. J Struct Biol. 2011 Dec;176(3):292-301. [PMID 21963792]

Intellectual Property: HHS Reference No. E-224-2011/0 — U.S. Provisional Patent Application No. 61/551,742 filed 26 Oct 2011

Related Technology: HHS Reference No. E-211-2005/0 — U.S. Patent Application No. 11/989,737 filed 29 Jan 2008, with corresponding applications in Europe, Canada, and Australia

Licensing Contact: Kevin W. Chang, Ph.D.; 301-435-5018;
changke@mail.nih.gov

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Date

Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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